

Diagnostic Use of Lung Ultrasound for Suspected Pneumonia in Nepal

NCT02949141

May 16, 2016

Introduction

Pneumonia is one of the leading causes of death worldwide.[1] In Nepal, pneumonia is the leading cause of death.[1, 2] These deaths can be prevented with early diagnosis that allows patients to get appropriate treatment. The diagnosis, however, is not always clear on presentation to health care facilities. Diagnosis can often depend on the patient's ability to pay and the facilities diagnostic capabilities. Imaging for pneumonia usually includes a chest x-ray (CXR), or in some cases, a thoracic computed tomography (CT) scan. While the latter is the diagnostic gold standard, it is associated with high costs and high doses of radiation.[3, 4] Therefore, chest x-ray continues to be the main diagnostic modality for pneumonia despite its low sensitivity.[4, 5]

Several studies in high-income countries have shown ultrasound to be a reliable tool to diagnose pneumonia with a higher sensitivity and specificity than chest x-ray.[6-10] Ultrasound is a safe, portable and inexpensive diagnostic modality that is widely used in resource-limited countries. [11] However, use of ultrasound to diagnose pneumonia in resource-limited settings like Nepal has not yet been studied.

This study will allow us to determine if clinicians in Nepal are able to use ultrasound to diagnose pneumonia. Given the ease, portability, and relative ease of teaching ultrasound, this would be potential technology available for many clinicians throughout Nepal to use for patients presenting with suspected pneumonia. This would be especially useful in remote areas where clinicians have limited access to x-rays.

To determine effectiveness of ultrasound compared to chest X-ray for diagnosis of pneumonia in patients presenting to an emergency department in Nepal.

IV. Methodology

Study Design: A prospective, convenience sample of patients presenting with suspected pneumonia when trained ultrasound physicians are present in the Patan Hospital Emergency Department was performed in Kathmandu, Nepal. This study was done in partnership with Patan Hospital Emergency Department with the ethical approval from Nepal Health Research Council.

Study Setting: Located in the Kathmandu valley, Patan Hospital is a large urban hospital with 35-bed Emergency Department that sees approximately 32,000 patients per year.

Study Population:

Inclusion criteria: Patients presenting to the Emergency Department at Patan Hospital age 18 or older with suspected signs of pneumonia with at least three of the following: temperature greater than 38 or history of fever, cough, dyspnea, heart rate higher than 100 beats per minute, tachypnea (RR>20), or oxygen saturation lower than 92%.

Exclusion criteria: Children will be excluded from the study. Also, ultrasound studies completed by physicians not trained in lung ultrasound will not be included.

Study Protocol:

Prior to the enrolling patients, clinicians in the ED will save lung ultrasound exams and interpret their exams. These exams will then reviewed by an ultrasonographer to ensure adequate skill in lung ultrasonography. A kappa analysis of these scans will be performed. If kappa <0.6, we will review lung ultrasound with these clinicians and repeat above evaluation until kappa of 0.6 is achieved.

For patients meeting inclusion criteria, consent will be obtained from the patient to participate in the study. Consent will include explanation of use of bedside ultrasound and chest CT scan for diagnosis of their condition. This consent will also include explanation of risks and benefits in Nepali (see attached consent form). These examinations will be provided free of charge to the patient.

The physician will record patient demographics, symptoms, lung exam findings, and pre-test probability of pneumonia (low, intermediate, high) on the data form (see attached).

After initial clinical evaluation, a bedside lung ultrasound will be performed. A Sonosite M Turbo (Fujifilm Sonosite, Inc.) ultrasound machine will be used. The ultrasound examination will include ten views, two anterior views and two lateral views (one including the costophrenic angle), and one posterior view on both chest walls. The physician will then record findings and diagnosis on the data entry form along with their post-test probability of pneumonia (low, intermediate, high).

Patients will get a chest x-ray as a part of the standard evaluation. These readings will be recorded on the data sheet. Patients will then undergo a chest CT, as the diagnostic standard to evaluate for pneumonia. The CT will be read by a radiologist. The radiologist will be blinded to the results of the previous studies. The reading and diagnosis will be recorded on the data form.

Statistical Analysis

The performance of ultrasound for diagnosis of pneumonia will be expressed as sensitivity, specificity, and likelihood ratios. Since the sensitivity of ultrasound is estimated around 90%, in order to detect a 20% difference based on a CXR sensitivity of 70%, 62 patients will be needed. McNemar's test will be used to evaluate any statistical difference in sensitivity between CXR and US.

1. **The 10 leading causes of death by country income group**
[<http://www.who.int/mediacentre/factsheets/fs310/en/index1.html>]
2. **Global Burden of Diseases: Nepal**
[http://www.healthdata.org/sites/default/files/files/country_profiles/GBD/ihme_gbd_country_report_nepal.pdf]
3. Brenner DJ, Hall EJ: **Computed tomography--an increasing source of radiation exposure.** *The New England journal of medicine* 2007, **357**(22):2277-2284.
4. Syrjala H, Broas M, Suramo I, Ojala A, Lahde S: **High-resolution computed tomography for the diagnosis of community-acquired pneumonia.** *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America* 1998, **27**(2):358-363.
5. Hagaman JT, Rouan GW, Shipley RT, Panos RJ: **Admission chest radiograph lacks sensitivity in the diagnosis of community-acquired pneumonia.** *The American journal of the medical sciences* 2009, **337**(4):236-240.
6. Bourcier JE, Paquet J, Seinger M, Gallard E, Redonnet JP, Cheddadi F, Garnier D, Bourgeois JM, Geeraerts T: **Performance comparison of lung ultrasound and chest x-ray for the diagnosis of pneumonia in the ED.** *The American journal of emergency medicine* 2014, **32**(2):115-118.
7. Cortellaro F, Colombo S, Coen D, Duca PG: **Lung ultrasound is an accurate diagnostic tool for the diagnosis of pneumonia in the emergency department.** *Emergency medicine journal : EMJ* 2012, **29**(1):19-23.
8. Reissig A, Copetti R, Mathis G, Mempel C, Schuler A, Zechner P, Aliberti S, Neumann R, Kroegel C, Hoyer H: **Lung ultrasound in the diagnosis and follow-up of community-acquired pneumonia: a prospective, multicenter, diagnostic accuracy study.** *Chest* 2012, **142**(4):965-972.
9. Liu XL, Lian R, Tao YK, Gu CD, Zhang GQ: **Lung ultrasonography: an effective way to diagnose community-acquired pneumonia.** *Emergency medicine journal : EMJ* 2015, **32**(6):433-438.
10. Pereda MA, Chavez MA, Hooper-Miele CC, Gilman RH, Steinhoff MC, Ellington LE, Gross M, Price C, Tielsch JM, Checkley W: **Lung ultrasound for the diagnosis of pneumonia in children: a meta-analysis.** *Pediatrics* 2015, **135**(4):714-722.
11. Sippel S, Muruganandan K, Levine A, Shah S: **Review article: Use of ultrasound in the developing world.** *International journal of emergency medicine* 2011, **4**:72.